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10/721,222	11/26/2003	Raymond H. Heininger		6261

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EXAMINER	
CHYN, AILEEN	
ART UNIT	**PAPER NUMBER**
3715	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,222	HEININGER ET AL.	
	Examiner	Art Unit	
	Aileen Chyn	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

2. Claim 5 is objected to because of the following informalities: On line 3, "CT" and "MRI" are acronyms, which should be defined in the claim at first use. Appropriate correction is required.

Claim 11 is objected to because of the following informalities: On line 2, "VTE" is an acronym, which should be defined in the claim at first use. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4, 7 and 9-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., "Ramshaw" (US Pat. No. 5,791, 907) in view of Alexander et al., "Alexander" (US Pat. No. 6,929,481 B1).

With respect to claim 1, Ramshaw discloses a process comprising:

obtaining available operating procedures for equipment used in treatment and training facilities (abstract, "An interactive medical training device ... to provide

education and training in medical procedures", Figure 3A and 8A depict a list of possible procudes)

creating a computer software representation of said equipment operating procedures (abstract, "the computer system is programmed to provide education and training in medical procedures");

obtaining operating parameters for each piece of equipment (Figures 5A and 5B describe operating parameters for each piece of equipment);

creating computer software representative of the operating parameters for each piece of equipment(Figures 5A and 5B describe operating parameters for each piece of equipment);

establishing optimum operation procedures from experts to be followed for various given patient problems (Figures 7B , 7C and 8B depict optimum operation procedures from experts to be followed);

creating computer software representation of said optimum operating procedures (abstract, "if the input is correct the system will display a prerecorded video segment illustrating the next step of the surgical procedure.");

presenting a trainee with a practical problem that involves use of said equipment in said treatment facility (abstract, "The system requests a user to input information relating to a next step in the surgical procedure, which advantageously keeps the user engaged in the training session."; Figures 10 and 11 depict presenting the trainee with a practical problem);

obtaining the procedures used by the trainee to solve the problem presented (abstract, " The user inputs the requested information through an input device, such as a mouse, a keyboard, a touch-sensitive screen, or other input device.");

comparing the procedures followed by the trainee with the optimum operating procedures established by the experts (abstract, "The system then receives and interprets the user input and informs the user as to whether the input is correct.").

However Ramshaw does not explicitly disclose radiological equipment.

Alexander discloses a process for training healthcare providers procedures for using radiological equipment (col. 8, lines 23-40, "An overall system for simulating medical procedures...The computer system simulates, via software, an endoscopic or other medical procedure (e.g., an interventional radiology procedure), while displaying a simulated particular bodily region of interest.", wherein "RADIOLOGY PROCEDURE" inherently requires "RADIOLOGICAL EQUIPMENT").

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a radiological equipment as disclosed by Alexander into the system for interactive medical training as disclosed by Ramshaw to provide an enhanced realistic simulation of that procedure including peripherals in the form of mock or actual medical instruments (Alexander, col. 1, lines 38-43). One of ordinary skill in the art would be motivated to make the aforementioned combination with reasonable expectation of success.

Claim 2 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above

in claim 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: ...create computer-generated three-dimensional full-scale interactive virtual images (Ramshaw, col. 7, lines 36-37, wherein "PHOTOGRAPHIC IMAGES" are analogous to "THREE-DIMENSIONAL", Figures 7B, 7C and 9C depict the virtual images);

Claim 3 is rejected for the reasons set forth hereinabove for claim 2 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claim 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: simulating the... trainee interact with said computer-generated three-dimensional image (Ramshaw, col. 8, line 55, wherein, the user choosing to "OBSERVE" the video is a form of "INTERACTION");

The subject matter of claim 4 is rejected in the analysis above for claims 2 and 3, wherein "VIRTUAL REALITY IMAGE" is analogous to, "a computer simulation of a real or imaginary system".

Claim 7 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claim 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: providing a virtual manikin for student problem solution interaction (Ramshaw, Figures 7B and 7C depict a virtual body for a student problem interaction.)

However Ramshaw does not specifically disclose a virtual reality image.

Alexander discloses a virtual manikin and force-feedback (abstract and Figure 1 depicts a virtual manikin, col. 12, line 36, wherein "VIRTUAL PATIENT" is analogous to "VIRTUAL MANIKIN")

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a virtual manikin and force-feedback as disclosed by Alexander into the system for interactive medical training as disclosed by Ramshaw to provide the mock bodily region of interest may be pivotable to simulate various patient orientations (Alexander, col. 6, lines 19-21). One of ordinary skill in the art would be motivated to make the aforementioned combination with reasonable expectation of success.

Claim 9 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and 7 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: providing screen viewing and evaluation of virtual imaging that results from trainee techniques used (Ramshaw, Figures 8B, Figures 10 and 11, Figure 13B (element 155) and abstract)

Claim 10 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and 7 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including:

providing a virtual environment ...to simulate accessing and servicing of radiological equipment used (Ramshaw, Figures 5A and 5B).

Claim 11 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and 7 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: obtaining available information ...on radiology equipment drawings, measurements and digital images of the radiological equipment used (Ramshaw, Figures 7B, 7C, 8B and Figures 10F; and Alexander, Figure 10).

The subject matter of claim 12 is rejected in the analysis above for claim 1.

Claim 13 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: obtaining and creating...patient problems each piece of equipment can assist in diagnosing (Ramshaw, Figures 8A and 8B disclose a list of procedures for diagnosing patient problems and Figure 9B disclose an instrument list for diagnosis).

Claim 14 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including:

obtaining expert opinion on the best equipment to use for specific patient problems (Ramshaw, Figure 9A and 9B, wherein "HINT" is analogous to "EXPERT OPINION");

creating computer software representation of the best equipment to be used for evaluating patient problems (Ramshaw, Figure 9C).

Claim 15 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and 7 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: obtaining and creating....expert interpretation of results obtained from the radiological equipment used (Ramshaw, abstract, Figure 12 and col. 12, lines 12-16, wherein "INSTRUCTOR APPEARS AND INSTRUCTS THE USER....AN INCORRECT CHOICE" is analogous to "EXPERT INTERPRETATION OF RESULTS").

Claims 16 and 17 are rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including Interfacing with ... Software for recording, documenting and scoring the procedures and tests performed by the trainee (Ramshaw, Figure 3A, abstract, col. 13, lines 11-13, col. 13, lines 55-63).

However Ramshaw does not specifically disclose a recording the procedures performed by the trainee.

Alexander discloses a recording the procedures performed by the trainee (col. 12, lines 9-20, "virtual camera ... control a simulated recording system that may capture video and/or still images from the monitor system.", wherein the "CAMERA RECORDING SYSTEM" is analogous to "RECORDING PROCEDURES PERFORMED BY TRAINEE"

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate recording the procedures performed by the trainee as disclosed by Alexander into the system for interactive medical training as disclosed by Ramshaw to provide capture of desired simulation. One of ordinary skill in the art would be motivated to make the aforementioned combination with reasonable expectation of success.

The subject matter of claim 18 is rejected in the analysis above for claims 9 and 14.

The subject matter of claim 20 is rejected in the analysis above for claim 9.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., "Ramshaw" (US Pat. No. 5,791, 907) in view of Alexander et al., "Alexander" (US Pat. No. 6,929,481 B1) and further in view of Kimchy et al., "Kimchy" (US Pat. Pub. US 2004/0015075 A1).

Claim 5 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process

including: obtaining said available information on radiological equipment (Ramshaw, Figures 5A and 5B).

However the combination of Ramshaw and Alexander do not explicitly disclose radiological equipment so as to include x-ray, CT and MRI, ultrasound, nuclear medicine, cardiac catheterization, mammography, positron emission tomography.

Kimchy discloses radiological equipment so as to include x-ray, CT and MRI, ultrasound, nuclear medicine, cardiac catheterization, mammography, positron emission tomography. (section [0170], "Imaging system 200 also includes a medical imaging system 208, such as, but not limited to, computed or computerized tomography (CT), magnetic resonance imaging (MRI), ultrasound imaging, positron emission tomography (PET)..."; section [0050], " gamma camera employed in nuclear imaging", wherein, "NUCLEAR IMAGING" is analogous to "NUCLEAR MEDICINE"; section [0052], "cardiac catheter,"; section [0023], "mammography");

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate radiological equipment so as to include x-ray, CT and MRI, ultrasound, nuclear medicine, cardiac catheterization, mammography, positron emission tomography as disclosed by Kimchy into the system and process for interactive radiological training as disclosed by the combination of Ramshaw and Alexander to provide medical imaging used to build computer models which allow doctors to design minimally-invasive or open surgical procedures with imaging modalities also used to guide surgeons to the target area inside the patient's body, in the operation room during the surgical procedure (section [0026]). One of ordinary skill

in the art would be motivated to make the aforementioned combination with reasonable expectation of success.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., "Ramshaw" (US Pat. No. 5,791, 907) in view of Alexander et al., "Alexander" (US Pat. No. 6,929,481 B1) and further in view of Eggert et al., "Eggert" (US Pat. No. 6,193,519 B1).

Claim 6 is rejected for the reasons set forth hereinabove for claim 1 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process for creating computer software representation to support simulation of the mandatory and elective radiological procedures (Alexander, col. 8, lines 23-40 discloses radiological procedures, wherein "INTERVENTIONAL RADIOLOGY PROCEDURE" inherently includes "MANDATORY AND ELECTIVE RADIOLOGICAL PROCEDURES".)

However the combination of Ramshaw and Alexander do not explicitly disclose the American Registry of Radiologic Technologists certification requirements.

Eggert discloses registry guidelines and certification requirements (col. 7, lines 20-26, "Training program...program 14 follow BLS and ACLS guidelines set forth by the American Heart Association", wherein, "BLS and ACLS" are analogous to "CERTIFICATION REQUIREMENTS" and "AMERICAN HEART ASSOCIATION" is analogous to an American Registry for certification requirements.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate registry guidelines and certification requirements disclosed by Eggert into the system and process for interactive radiological training as disclosed by the combination of Ramshaw and Alexander to provide an interactive computerized education system which for providing different interactive training sessions involving patient care protocols (Eggert, col. 2, lines 22-23 and 34-35). One of ordinary skill in the art would be motivated to make the aforementioned combination with reasonable expectation of success.

7. Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramshaw et al., "Ramshaw" (US Pat. No. 5,791, 907) in view of Alexander et al., "Alexander" (US Pat. No. 6,929,481 B1) and further in view of Pugh (US Pat. Pub. US 2003/0031993 A1).

Claim 8 is rejected for the reasons set forth hereinabove for claim 7 and is also rejected for the reasons set forth hereinabove for the same limitations as set forth above in claims 1 and 7 and therefore the examiner maintains the same line of reasoning and furthermore the combination of Ramshaw and Alexander disclose a process including: manikin interaction to demonstrate trainee competence (Alexander, abstract and Figure 1 depicts a virtual manikin, col. 12, line 36).

However the combination of Ramshaw and Alexander do not explicitly disclose incorporating force-feedback gloves and sensor-enabling physical manikin interaction to demonstrate trainee competence.

Pugh discloses incorporating force-feedback gloves and sensor-enabling physical manikin...(section [0059], "To interact with the system, user 107 will possess a pair of three-dimensional glasses 109 and virtual-reality or haptic feedback gloves 111", wherein, "virtual-reality or haptic feedback gloves" is analogous to "FORCE-FEEDBACK GLOVES"; section [0037], "Manikin 14 also has tactile sensors 16 and 20 located in cavity 11 and on surface 15, respectively, so as to generate a signal in response to manual contact with these locations.");

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate force-feedback gloves and a sensor-enabling physical manikin as disclosed by Pugh into the system and process for interactive radiological training as disclosed by the combination of Ramshaw and Alexander to provide a training system and method that provides immediate feedback to students using direct manual contact with an organ or body surface. The system provides for objective assessment and individualized feedback that instructors alone cannot give.(section [0004]). One of ordinary skill in the art would be motivated to make the aforementioned combination with reasonable expectation of success.

The subject matter of claim 19 is rejected in the analysis above for claims 7 and 8.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Eggert et al. (U.S. Pat. No. 5,853,292) discloses a manikin with virtual instruments;

Bailey et al. (U.S. Pat. No. 6,739,877 B2) discloses radiological procedure with MRI in a team simulation model;

Hon (U.S. Pat. No. 4,360,345) discloses a procedural steps in a video; and

Hasson (U.S. Pat. No. 5,947,743) discloses a simulation of medical procedure using instruments.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aileen Chyn whose telephone number is 571-272-7176. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Monica Carter can be reached on (571) 272-4475. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 4, 2006
A.C.

Monica S. Carter
MONICA CARTER
SUPERVISORY PATENT EXAMINER